



INTRODUCTORY NOTE by Consumers Union and Center for Democracy & Technology: Guideline 2.1 below is the guideline posted with the Advisory Board's agenda items for its meeting on October 12, 2010, and subsequently adopted by vote of the Advisory Board at that meeting. We have interlineated amendments that would make this guideline more consistent with the Privacy and Security Tiger Team's recommendations, but this document should be read in conjunction with (a) our cover letter to Secretary Belshé and the Advisory Board, dated December 5, 2010, and (b) our briefing paper entitled "A Sound Approach to Patient Consent, Privacy, and Security for Electronic Health Information Exchange in California", dated October 6, 2010, for a complete understanding of the amendments proposed below, their benefits, and their limitations. For example, as we note in our cover letter, the Tiger Team's recommendations do not consider patient consent in isolation but in the comprehensive context of fair information practices and their interconnected privacy and security protections.

One necessary amendment does not occur within Guideline 2.1 below, but in Guideline 9.0 Definitions, so we provide it here:

Electronic Health Information Exchange (eHIE): A formal electronic health information exchange infrastructure formed to facilitate the exchange of electronic health information among unrelated or unaffiliated healthcare entities for treatment, care coordination, and other agreed-upon health care purposes. An eHIE is characterized by agreement among participants to allow one another to have access to identifiable health information from clinical records in accordance with common terms of participation.

**Deleted:** The electronic movement of health related data and information among organizations.

**CONTEXT:** The following document is derived from a set of recommended principles developed by the California Privacy and Security Advisory Board (CalPSAB) at its June 9, 2010 meeting to be components of a consent policy. Those principles are provided below. It does not reflect or adhere to the legal recommendations provided by CalOHII for an HIE patient consent policy. Following the principles are the preamble and guidelines resulting from work of the task group of CalPSAB members who volunteered to work on the proposed guidelines for HIE Patient Consent that would reflect the principles.

## Proposed HIE Patient Consent Policy Principles

### Components to Include in Policy

- Opt In Model – entry points may be: provider/provider group specific, IPA specific, HIO specific, or plan specific, etc. Should be done in advance of making patient's information available via an electronic health information exchange.
- Highest level entity point – available system wide – not conducted at each point of service.

\* Organized Health Care Arrangements, as defined in the HIPAA Privacy Rule, and exchange among entities that share a corporate relationship or affiliation and therefore a common patient record should not be considered eHIEs for purposes of treatment, care coordination, and public health and quality reporting, per the Tiger Team's recommendations. The patient has prior notice and expectation of such joint arrangements as required by the Privacy Rule.



- Standardized across system
- Continuously in effect unless patient revokes (no annual re-up)
- Accommodate e-signature/web-enabled as appropriate
- Informing document should display and explain risks and benefits
- Break-the-glass allowed for patient inability to consent
- Conditional treatment/enrollment/eligibility allowed according to federal and state law
- All information in (no restrictions)
- Security and access standards should respond and cross-reference sensitive health information

**Components to Avoid in Policy**

- Multiple consent requirements (more than one consent taken)
- Policy that doesn't move forward with technology (for highly sensitive information)
- Cannot conflict with state and federal law



## Recommended Guideline Amendments for HIE Patient Consent

**Preamble to Section 2.1** *[to be presented as a separate part from the guidelines]*: It is the right of every individual to have their health information protected by entities that provide care to the individual. With proper privacy and security safeguards, confidential health information will only be shared with those who have a legitimate need to know. The protection and safeguarding of health information must allow entities to share health information to facilitate treatment of the individual. Limited uses of the information subsequent to treatment are also sometimes necessary, so long as the use is allowed in Federal law, California law, and these guidelines.

Examples of strategies for safeguarding individual health information, as provided in these guidelines, include, but are not limited to the following:

- Segregation of Sensitive Health Information
- Access controls
- Elimination of Overly Broad Requests and Disclosures
- Assurance of Appropriate Use and Disclosure
- Enforcement Mechanism

Technological limitations may not currently allow for the implementation of all of the above safeguards. Because of this, it is even more critical that an individual understand the benefits and risks of participation in an electronic health information exchange (eHIE) via an informed HIE consent procedure. HIE consent, in addition to being an individual's right to determine the use of his/her health information, is an educational component that allows an individual to make an informed decision about the treatment of his/her health information. The consent form provides documentation of the educational component and the individual's decision.

An individual has the right to choose to restrict or enable his/her individual health information to be exchanged via an eHIE as provided in these guidelines.

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2.1 HIE PATIENT CONSENT	
<b>2.1 Opt In Consent Required</b>	<u>Where, under the terms of participation in an eHIE or the entity's agreement with the eHIE, an entity would no longer control the decision to disclose a patient's information or the kind or volume of information to be disclosed, or where consent is otherwise required by federal or state law, no</u> individual health information shall be exchanged <u>via an eHIE</u> except as required by law if the entity does not obtain or verify an individual's <u>meaningful</u> consent through the procedure described below.
<b>2.1.1 Obtaining Consent</b>	Unless otherwise required by law, an individual shall provide written consent to electronically exchange his/her health information <u>via an eHIE</u> . An individual's <u>HIE</u> consent shall be made, unless otherwise required by law <sup>†</sup> :

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<sup>†</sup> 42 CFR part 2 implications



	<ul style="list-style-type: none"><li>• One time, unless revoked, or reinstated.</li><li>• At the appropriate point of contact with the individual as determined by his/her health care entity.</li></ul>	
<b>2.1.1.1 HIE CONSENT VERIFICATION</b>	<p>Before any individual's health information is exchanged <u>via an eHIE</u>, by an entity, the entity shall:</p> <ul style="list-style-type: none"><li>• Verify that the individual has explicitly agreed to have his/her health information exchanged <u>via an eHIE</u>, or</li><li>• Verify that the individual has been informed about his/her rights and choices concerning <u>participation in an eHIE</u>, and</li><li>• Obtain from the individual his/her explicit agreement by a signed consent form to have his/her health information exchanged <u>via an eHIE</u>.</li></ul>	<p>Deleted: electronically</p> <p>Deleted: electronically</p> <p>Deleted: the electronic exchange of his/her health information</p> <p>Deleted: electronically</p>
<b>2.1.1.2 EMERGENCY DEPARTMENT OPTIONS</b>	<p>An emergency department may obtain an individual's consent to have his/her individual health information exchanged <u>via an eHIE</u> on admittance to or at discharge from an emergency department. Consent is to be obtained before information is exchanged, except when complying with 2.1.1.3 Delayed Consent in Emergency Situations.</p> <p>When an emergency department chooses to obtain an individual's consent at discharge, the individual must be provided an opportunity to consent to having his/her individual health information exchanged <u>via an eHIE</u> before discharge or transfer from the facility.</p> <p>If the individual does not consent to having his/her individual health information exchanged <u>via an eHIE</u>, the entity shall not <u>make the individual's information available to or via the eHIE</u> for any purpose except as required by law.</p> <p>If an individual has not been given the opportunity to consent to having his/her individual health information exchanged <u>via an eHIE</u> and is incapacitated upon discharge or transfer from the facility, the individual must be given the opportunity to consent as soon as practicable.</p>	<p>Deleted: electronically</p> <p>Deleted: electronically</p> <p>Deleted: electronically disclose the individual health information</p> <p>Deleted: electronically</p>
<b>2.1.1.3 DELAYED CONSENT IN EMERGENCY SITUATIONS</b>	<p>An entity may electronically access an individual's health information <u>via an eHIE</u> without the individual's consent when the individual cannot consent due to his/her incapacity in an emergency treatment circumstance when:</p> <ul style="list-style-type: none"><li>(a) The individual has not previously explicitly denied or withheld consent to the exchange <u>via an eHIE</u> of their individual health information; and</li><li>(b) It is in the individual's best interest as determined by the treating health care provider, in the exercise of the treating health care provider's professional judgment.</li></ul> <p>The entity must inform the individual and provide an opportunity to consent to having his/her health information exchanged <u>via an eHIE</u> as soon as it becomes practicable to do so.</p> <p>If the individual fails to consent to electronically transmit his/her health</p>	<p>Deleted: electronic</p> <p>Deleted: electronically</p>



	information no information shall be <u>provided to or shared via an eHIE</u> .	<b>Deleted:</b> electronically transmitted, and health information previously electronically accessed may not continue to be electronically exchanged
<b>2.1.2 NO CONSENT FOR ANY MANDATED DISCLOSURE</b>	An entity may transmit <u>via an eHIE</u> without consent only the required data elements of individual health information required by law for public health reporting purposes. <i>(See Appendix A for a non-exhaustive listing of laws pertaining to public health purposes.)</i> The reporting shall not be transmitted <u>via eHIE</u> if the information cannot be limited to the required data elements.	<b>Deleted:</b> electronically <b>Deleted:</b> electronically
<b>2.1.3 DURATION OF HIE CONSENT</b>	A HIE consent shall remain in effect until revoked, updated, or a new entity has access to the individual health information through the electronic health exchange <sup>†</sup> .	
<b>2.1.4 MINORS AS INDIVIDUALS</b>	An entity shall obtain HIE consent from a minor when a minor is considered an individual for the purposes of these guidelines. In such circumstances, an entity shall not seek HIE consent from the parent or personal representative of the minor unless permitted by the minor. <i>(See section 1.4.4 for situations where a minor is considered an individual.)</i>	
<b>2.1.5 ALTERNATIVE TO CONSENT</b>	In situations when an individual has chosen not to have his/her individual health information exchanged <u>via an eHIE</u> , entities may seek to obtain the information <u>directly from the provider-record holder</u> as permitted by law through other methods, such as: telephone calls, fax's, hardcopy mail, etc.	<b>Deleted:</b> electronically
<b>2.1.6 INFORMING INDIVIDUALS OF HIE CONSENT</b>	An entity shall provide the individual a written notice and consent form in plain language that: a. Contains the informing requirements in section 2.1.6.1 below, and b. Is a separate document from all other information; or c. Is part of the Notice of Privacy Practices (NPP), if the HIE consent is a significantly distinct and apart from other language, separately signed and dated, and the entity orally communicates to the individual the significance of the HIE consent.	
<b>2.1.6.1 GENERAL INFORMING REQUIREMENTS</b>	An entity shall inform the individual: (a) When required by law, that data elements from the individual's health information will be transmitted <u>via an eHIE</u> . (b) That the individual has the right to enable or restrict transmission of his/her individual health information <u>via an eHIE</u> , except as required by law. (c) That a complete listing of entities that may collect and share their information <u>via an eHIE</u> , along with intermediary entities, is provided. (d) If the individual is incapacitated, that the treating provider may access individual health information <u>via an eHIE</u> if it is consistent with the individual's prior consent choice and the treating provider believes it is	<b>Deleted:</b> electronically <b>Deleted:</b> electronic

<sup>†</sup> 42 CFR Part 2 implications

	<p>in the individual's best interest.</p> <p>(e) About the benefits and risks associated with the exchange of health information <u>via an eHIE</u> are described.</p> <p>(f) That the individual may revoke his/her choice to participate in health information exchange <u>via an eHIE</u> at any time, the process for revoking the choice, and when that action will be effective.</p> <p>(g) That revocations of his/her choice to participate in health information exchange <u>via an eHIE</u> will not remove previously transmitted health information from current records, but will prevent future transmission <u>via an eHIE</u> of any individual health information.</p> <p>(h) That the individual's choice to include or exclude his/her individual health information from <u>an eHIE</u> shall not be construed to waive any privilege or right granted under federal, state, or local law or procedure.</p> <p>(i) That the laws of other states affect the privacy and security of the individual's health information when transmitted outside of California.</p> <p>(j) That the individual health information may not be redisclosed by the entity receiving the transmitted information unless authorized by law. [Reference: Civil Code Section 56.13]</p> <p><u>(k)</u> About the extent to which the entity has controls to limit the access to individual health information to specific content or specified categories of individuals or entities within and outside of the entity.</p> <p><u>(l)</u> About the extent to which the entity limits requests and disclosures of his/her individual health information to the information related directly to the purpose of the request.</p>	<p>Deleted: electronic</p> <p>Deleted: electronic</p> <p>Deleted: electronic</p> <p>Deleted: electronic</p> <p>Deleted: electronic transmission</p> <p>Deleted: &lt;#&gt;That the individual's sensitive health information may be exchanged which might include references to HIV status, alcohol and drug abuse treatment records, mental health records, genetic information, and other potentially sensitive information.¶</p> <p>Formatted: Bullets and Numbering</p>
<p><b><u>2.1.6.2 MEANINGFUL CONSENT</u></b></p>	<p><u>To ensure that the consent is meaningful, an entity shall:</u></p> <ul style="list-style-type: none"> <li>• <u>Allow the individual advance knowledge and time to make the decision on consent, e.g. outside of the urgent need for care.</u></li> <li>• <u>Not compel or use the consent for discriminatory purposes, e.g. condition receiving necessary medical services upon consenting to participation in an eHIE.</u></li> <li>• <u>Provide full transparency and education, so that the individual receives a clear explanation of the choice and its consequences, in consumer-friendly language that is conspicuous at the time of decision.</u></li> <li>• <u>Make the explanation and process commensurate with the circumstances, so that information or exchange that is more sensitive or inscrutable receives a more specific consent mechanism, and activities that depart significantly from reasonable patient expectations trigger a greater degree of patient education, time to make the consent decision, opportunity to discuss the decision with the provider, etc.</u></li> <li>• <u>Make the consent process consistent with reasonable patient</u></li> </ul>	





	<ul style="list-style-type: none"><li><a href="#">expectations for health, privacy, and safety.</a> <a href="#">Make the consent revocable at any time and explain the rights and terms of revocation under 2.1.7 Revocation of HIEconsent Decision and 2.1.8 Applicability of a Revocation.</a></li></ul>	<div>Formatted: Indent: Left: 0", Hanging: 0.44", Space Before: 0 pt, After: 0 pt, Line spacing: At least 12 pt, Don't hyphenate, Tabs: 0.44", Left + 0.88", Left + 2.56", Left + 2.83", Left + Not at 0.32"</div> <div>Deleted: the electronic</div>
<b>2.1.7 Revocation of HIEconsent Decision</b>	An individual has the right to revoke his/her consent to exchange of their health information <a href="#">via an eHIE</a> . An entity shall make the individual health information unavailable to <a href="#">an eHIE</a> , when an individual revokes his/her choice to have his/her individual health information transmitted <a href="#">via that eHIE</a> .	<div>Deleted: be electronically exchanged</div> <div>Deleted: electronically</div>
<b>2.1.8 Applicability of a Revocation</b>	A revocation of HIEconsent does not apply to individual health information transmitted prior to the revocation or to transmission of data elements of individual health information mandated by law for public health purposes.	
<b>2.1.9 Resolving Conflicting HIEconsents</b>	Entities, in consultation with the individual and/or the entities with whom the conflict exists, shall have a mechanism to identify and address conflicts concerning consent to the electronic exchange of individual health information. <i>[Reference: 45 C.F.R. § 164.508]</i>	
<b>2.1.10 Federal and State Laws</b>	An individual's choice to include or exclude his/her individual health information from exchange <a href="#">via an eHIE</a> shall not be construed to waive any privilege or right granted under federal, state, or local law or procedure. <i>[Reference: § 164.506 preamble discussion, October 2000 Final Regulations]</i>	<div>Deleted: electronic</div>
<b>2.1.11 Implementation Specifications</b>	An entity shall implement the requirements of Section 2.1 when <a href="#">the entity signs a participation agreement any eHIE</a> .	<div>Deleted: 2</div> <div>Formatted: Bullets and Numbering</div> <div>Deleted: any of the following first occur: ¶ With implementation of a new practice management or electronic health record system, or ¶ With major version upgrades (i.e., meaningful use upgrades) of existing practice management or electronic health record systems, or ¶ By January 1, 2016.</div>